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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,277	08/31/2000	E. Antonio Chiocca	0609.4880002/JAG/KRM	4747

7590            04/28/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/653,277	CHIOCCA ET AL.	
	<b>Examiner</b> Joseph T. Woitach	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 19 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4-12,34 and 35 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3,13-33 and 36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                         |                                                                                          |
|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.                                                |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2004 has been entered.

**DETAILED ACTION**

This application filed August 31, 2000, claims benefit to provisional application 60/151,621, filed August 31, 1999.

As requested in Applicants' request for continued examination Applicants' after final amendment filed November 19, 2003 has been entered. The specification has been amended. Claims 1, 13, 14, 30 and 31 have been amended. Claims 1-36 are pending.

***Election/Restriction***

Applicant's election with traverse of Group I, claims 1-3, 13-33 and 36, in Paper No. 13 was acknowledged. No new arguments are presented in Applicants' after final amendment. Therefore, the restriction requirement is maintained for the reasons of record and is maintained as **FINAL**.

Claims 1-36 are pending. Claims 4-12 and 34-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13. Claims 1-3, 13-33 and 36 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim objections***

Claims 13 and 30 objected to because they contain acronyms for genes/promoters which are not specifically recited in the specification is withdrawn.

The amendments to the claims has obviated the basis of the objection.

Claims 15, 24 and 30 are objected to because of the following informalities: the amendment to the specification identifying the deposit is noted, however the claims should be amended to indicate the specific designation number assigned Myb3.5, PTA-4963. More specifically, each of the claims are recite and are drawn to the ‘herpes viral mutant Myb34.5’ however what was deposited was only the vector. Amending the claims to recite the Patent Deposit Designation number at the end of the claim would obviate the basis of the objection.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 13, 16-23, 25-33 and 36 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating tumorigenic disease of the central nervous system and perfuse metastatic liver and colon cancer cells in a mammal comprising administering herpes mutant comprising: (a) an inactivating alteration in the  $\gamma$ 34.5 gene and (b) an insertion of a  $\gamma$ 34.5 gene under operatively linked to a B-myb promoter, does not reasonably provide enablement for treatment of other types of neoplastic cells or the use of other promoters is withdrawn.

Applicants' arguments have been fully considered and found persuasive.

Claims 1-3, 13-33 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, claim 1 has been amended from a vector containing two elements inactivated  $\gamma$ 34.5 and an inserted copy of  $\gamma$ 34.5, to a vector wherein it appears that a transcriptional control

element is operatively linked to mutated  $\gamma$ 34.5 gene. The only antecedent basis for ‘at least one copy of the  $\gamma$ 34.5 gene’ in the claim is to the one comprising ‘a deletion or inactivating mutation in both copies of the gene encoding g34.5’. The claims have been amended to delete the recitation that the ‘at least one copy of the  $\gamma$ 34.5 gene’ is ‘an insertion’, and the claim now reads on inserting a promoter in front of the deleted or inactivated copy of the gene encoding  $\gamma$ 34.5 which is not recited nor generally defined in the instant specification. Applicants point to page 14, lines 10-13 in support for the amendment (see Applicants’ amendment, page 12, Remarks section), however this portion of the specification indicates that a copy of the  $\gamma$ 34.5 gene is reintroduced under the transcriptional control of a promoter, not that transcriptional control element is inserted in front of the alter endogenous  $\gamma$ 34.5 gene sequence. Moreover, a general review of the teachings of the instant specification indicates that this embodiment is counter the disclosed invention which is to introduce and provide for the expression of a functional  $\gamma$ 34.5 gene product in a tissue or cell specific manner.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-3, 13-33 and 36 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re

Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 13-33 and 36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear how operatively linking one of the deleted or inactivated copies of the  $\gamma$ 34.5 to a cell-specific and/or tumor-specific promoter will allow for specific targeting. Without a functional copy of the  $\gamma$ 34.5 the viral mutant will not be selective. More clearly indicating the functional elements contained in the claimed mutant vector will obviate the basis of the rejection.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). In the instant case, the claims have been amended to delete the recitation that the ‘at least one copy of the  $\gamma$ 34.5 gene’ is ‘an insertion’, and the claim now reads on inserting a promoter in front of the deleted or inactivated copy of the gene encoding  $\gamma$ 34.5 which is not recited nor generally defined in the instant specification.

Appropriate correction is required.

***Conclusion***

No claim is allowed. The claims are free of the art of record, however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

*Joe Woitach*  
AU1632